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EXAMINER	
LILLING,H	
ART UNIT	**PAPER NUMBER**
1808	

18N2/1002

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DATE MAILED: 10/02/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire ONE month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-44 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☐ Claims _____ are rejected.
5. ☐ Claims _____ are objected to.
6. ☒ Claims 1-44 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

Ser No. 08/259413

EXAMINER'S ACTION

15. Claims 1-44 are present in the instant application.

16. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-11 and 43, drawn to a biologically-active conjugate and pharmaceutical composition containing the compound, classified in Classes 514 and 530, numerous subclasses which includes 357, 404 depending upon the biologically active molecule.

II. Claims 12-14, drawn to a method of preparing a biologically-active conjugate, classified in numerous Classes depending upon the polymer and the biologically active molecule which includes Class 435 and Class 530 and numerous subclasses.

III. Claims 15-33 and 44, drawn to substantially purified compounds of R_1-X-R_2 and pharmaceutical composition containing the compounds, classified in numerous Classes and subclasses based on non-peptidic polymer and R's groupings.

IV. Claims 34-37, drawn to a water-soluble polymer having a reactive NHS-ester and a reactive Michael acceptor, classified in several Classes which includes Class 524, 525 or 528 depending upon the polymer.

V. Claims 38-42, drawn to a method of preparing a compound R_1-X-R_2 , classified in numerous Classes depending upon the reactants and the polymers involved.

The inventions are distinct, each from the other because of the following reasons:

Inventions II/V and I/III are of varying scope that does not require the same specifics of the products as claimed, e.g. the method claims do not require that the active sulfone group to be reacted with the thiol moiety nor does Invention III require that X reacts with R_1 and R_2 but can be obtained by another method.

Inventions II/V and I/III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case, the process for preparing the products as claimed can be made by another and materially different process which includes different substrates which reacts to form the same compounds, e.g. XR_1H_2 + R_2-----then dehydrogenate to form the same compound.

Invention IV is separate and patentably distinct from that of Invention I or Invention III products.

Invention I is separate and patentably distinct from that of Invention III.

Method Claimed Invention II and V are separate and patentably distinct from each other.

17. This application contains claims directed to the following patentably distinct species of the claimed invention:

i.> Whereby the biologically active molecule is selected from the group consisting of

i. from a tumor necrosis factor (TNF) inhibitor
ii. IL-1 inhibitor
iii. CR1
iv. PDGF receptor
v. IL-2
vi. exon 6 peptide of PDGF

ii.> Whereby the Michael acceptors are

a. vinyl sulfone

b. maleimide

c. combination of a. and b.

iii.> Whereby the active sulfone is selected from the group consisting of

x. vinyl sulfone

y. chloroethyl sulfone.

iv. Whereby the polymer is selected from the group consisting of

1. polyalkylene oxides

2. polyoxyethylated polyols

3. polyolefinic alcohols

18. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If

claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

19. Claims 1, 12, 15 and 34 are generic to a plurality of disclosed patentably distinct species comprising

A. The biologically active molecule is selected from

i. synthetic

ii. naturally occurring

further election which includes:

1. vitamins

2. nutrients

3. nucleic acids

4. amino acids

5. polypeptides

iii. modified naturally occurring molecule.

5a. TNF

5b. IL-receptors

5c. IGFbps

5d. CTLA4

5e. exon PDGF

5f. GDNF]

6g. CTNF

6h. IL-4r

6i. IL-2r

6. enzyme co-factors

7. steroids

8. carbohydrates

9. organic species -hepain

10. metal containing agents

11. receptor antagonists

12. binding proteins

13. receptors or portions of receptors,

14. extracellular matrix proteins

15. cell surface molecules

16. antigens

17. haptens

18. targeting groups

19. chelating agents.

B. The polymers of the invention selected from water soluble polymers of PEG or hydrophilic polymers selected from the group consisting of:

ia. PEG

ib. PPG

ic. POG or polyoxyethylated polyols

id. PVA

ie. polyoxyethlated sorbitol or glucose,

further that the polymer is selected from

w. homopolymer

x. random polymer

y. block polymer

z. terpolymer

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

It is noted that each of the groupings requires a separate search and examination in the patented shoes as well as for the data bank bases.

20. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, have acquired a separate status in the art because of their recognized divergent subject matter and the search required for one invention is not required for the other invention, thusly the restriction for examination purposes as indicated is proper.

21. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

22. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

23. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is (703) 308-2034 and fax number (Art Unit 1808) is (703) 308-0294 Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

H.J.Lilling: HJL
(703) 308-2034
Art Unit **1808**
September 27, 1995

HERBERT J. LILLING
PATENT EXAMINER
GROUP 150 - ART UNIT 1808